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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JANG, CHRISTIAN YONGKYUN

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

03/31/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,178	Applicant(s) GAVRIELY ET AL.	
	Examiner CHRISTIAN Y. JANG	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 3rd, 2009 has been entered.

Claim Objections

2. Claims 18-27 are objected to because of the following informalities: Claims 18-27 are dependent upon cancelled claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 17-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. As to claim 17, the claim language recites "breathing is selected from the group including inspiration, expiration, the pauses between them, and any combinations

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thereof". However, the specification fails to show breathing selected from a post-inspiratory pause, just a post-expiratory pause. In addition, the specification fails to provide support for a cardio/pulmonary system selected from a group including cardio vascular system, lungs, and the thorax.

6. As to claim 18, there is no support for pressure changes in the cardio/pulmonary system selected from intrathoracic pressure and hemodynamic pressure.

7. As to claim 19, there is no support for intrathoracic pressure changes caused by any cause selected from "airway resistance, asthma, and resistive breathing".

8. As to claims 20 and 21, there is no support for where changes in intrathoracic pressure are caused by changes in compliance and said compliances are caused by congestive heart failure.

9. As to claim 22, there is no support for changes in intrathoracic pressure being caused by positive pressure artificial ventilation.

10. As to claim 26, there is no support for WBV being determined by calculating the ensemble average in the domains separated from group of domains including time domain and frequency domain.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 17-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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13. As to claim 17, the claim language recites "segmenting ... raw respiratory and ... raw heart beating sounds". However, later, the claim recites that the heart beating sounds are selected from a group including "first heart sound, second heart sound, and any combinations thereof". Since the first step includes the "identifying" of heart beating sounds, which is selected from the group, it implies that segmentation (in the event that S1 or S2 has been selected) has already been achieved prior to the second step, which calls for the segmentation. The language regarding breathing sounds also has the equivalent problem.

14. As to claims 18-24, the claim language modifies and further limits the preamble. For reasons stated in the Response to Arguments (see further below), the preamble has given no patentable weight. As such, further modifications given to the preamble also hold no patentable weight, and as such, it renders the claims indefinite. For purposes of examination, these claim limitations will be treated to be equivalent to intended use only.

15. Claim 26 recites the limitation "the ensemble average" in line 3. There is insufficient antecedent basis for this limitation in the claim. In addition, it is unclear what is meant by ensemble average including the time domain.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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17. Claims 17-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapiro et al. (USP #5,957,866).

18. As to claims 17 and 28, Shapiro teaches a method and corresponding device comprising the identifying and segmenting of breathing and heart beating sounds (col. 3, lines 47-49), classifying said segments (col. 4 lines 46-51), extracting the time dependent features of said classes and comparing them to determine the significance of the deviation of a set of said features from the baseline (Abs; col. 7 line 45 to col. 8 line 44). The heart sounds include the first and second heart sounds (col. 1, lines 36-58). The breathing includes inspiration (col. 6, lines 40-50). The pulmonary system includes the lungs (col. 2 lines 52-64).

19. As to claims 18-24, Shapiro teaches that the heart sounds correspond to changes in hemodynamic pressure (col. 1 line 66 to col. 2, line 13). In addition, Shapiro teaches that the changes in the timing relationship can indicate a physical problem indicating some physical pathology. As changes in intrathoracic pressure due to various causes such as asthma, airway resistance, resistive breathing, change in compliance, congestive heart failure, artificial ventilation, and blood shock are well known reasons of pathological symptoms, the method taught by Shapiro can be utilized in any of these intended uses to determine changes in the timing relationship of heart beat and respiratory sounds.

20. As to claim 25, Shapiro teaches the use of the amplitude of heart sounds (col. 5, lines 45-58).

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21. As to claim 26, Shapiro teaches the use of averaging of a frequency domain (col. 3, lines 50-56; col. 5, lines 13-31).

22. As to claim 27, Shapiro teaches the measurement of changes from the frequency contents (col. 3, lines 50-56; Fig. 8B).

Response to Arguments

23. Applicant's arguments with respect to claims 17-28 have been considered but are moot in view of the new ground(s) of rejection.

24. In response to applicant's arguments, the recitation "for utilization of within breath variability (WBV) of the heart sounds for assessing pressure changes in the cardio/pulmonary system" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). There is no step in the claimed method which allows for the assessment of pressure changes in the cardio/pulmonary system.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is

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(571)270-3820. The examiner can normally be reached on Mon. - Fri. (8AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CJ
/C. Y. J./
Examiner, Art Unit 3735
3/27/09

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735